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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,438	11/14/2003	Douglas G. Evans	KN P 0131	9636

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EXAMINER	
BLANCO, JAVIER G	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,438	EVANS ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of the legend for Figure 3 (previously Figure 2L) in the reply filed on November 12, 2004 is acknowledged.

2. Applicants' amendment of claims 1, 2, 23-25, 29, 30, and 34 in the reply filed on November 12, 2004 is acknowledged.

3. Applicants' addition of claim 35 in the reply filed on November 12, 2004 is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-9, 17-19, 22-26, and 30-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nigam (US 4,948,540; cited in Applicants' IDS).

Nigam discloses an implant for the repair and regeneration of tissue. Said implant comprises a conformable (see column 1, line 65 to column 2, line 14) matrix containing natural (= native) insoluble collagen and soluble collagen (see column 2, lines 29-65). Said matrix further comprises a therapeutic agent/drug (see column 2, lines 20-22).

6. Claims 1, 2, and 4-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyders, Jr. (US 5,425,769; cited in Applicants' IDS).

Snyders, Jr. discloses an implant for the repair and regeneration of tissue (particularly bone/cartilage). Said implant comprises a matrix, a binder/carrier, and ceramic material. Said matrix comprises collagen fibers (see column 4, lines 11-15). Said binder/carrier can act as a porosifying/foaming agent and includes biodegradable polymer such as polylactic acid or polyglycolic acid (see column 7, lines 49-55). Said porosifying/foaming agent could also comprise plaster of Paris (a calcium mineral). The ceramic material comprises calcium phosphates (see column 6, lines 44-49). The implant can further comprise growth factors, bone chips, bone marrow, and/or therapeutic agents/drugs (see column 6, lines 49-57; column 7, lines 32-45; column 8, lines 48-59). The implant is delivered/introduced to a target site by a variety of means (e.g., a syringe; see column 5, line 66 to column 6, line 12). The ratios of collagen fibers to binder/carrier are disclosed in column 8, lines 1-22. The implant has a paste consistency (see column 5, lines 25-57) and can be tailored to a variety of applications such as precast, moldable, or injectable alone or as a delivery vehicle (see column 5, lines 25-37; column 5, line 66 to column 6, line 7).

7. Claims 1-14, 17-19, 22-28, 30, 34, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sierra (US 6,110,484; cited in Applicants' IDS).

Sierra discloses an implant for the repair and regeneration of tissue. Said implant comprises a matrix (disclosed as a support network in column 3, lines 48-50), a porosifying agent, and ceramic material. Said matrix comprises collagen that has not been chemically treated (see column 4, lines 5-6, lines 37-40, and lines 45-47). Said porosifying agent includes a

biodegradable polymer such as gelatin, gelatinized collagen, or collagen (see column 4, lines 20-23) in the form of solid, gel, or hollow microspheres (see column 3, lines 30-33; column 4, lines 20-35; see Examples). The ceramic material comprises calcium sulfates, calcium phosphates, and the like (see column 5, line 66 to column 6, line 1). The implant can further comprise growth factors and/or therapeutic agents/drugs (see column 4, lines 48-67). The implant is delivered/introduced to a target site by a variety of means (e.g., a syringe; see column 7, lines 11-20; column 8, lines 14-15). The implant is conformable (see column 1, lines 25-27) and is capable of solidifying when being cast or of solidifying and polymerizing in situ (see column 3, lines 65-66).

8. Claims 1-35 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yamamoto et al. (US 2002/0183855; cited in Applicants' IDS).

Yamamoto et al. disclose an implant for the repair or regeneration of tissue (see entire document). Said implant is porous, biodegradable, three-dimensionally fixed, has shape memory, and maintains physical/structural integrity and porosity after been implanted (see entire document).

At least a first component of the implant is a non-soluble ceramic microgranules/microparticulate (i.e., calcium phosphate, hydroxyapatite; see page 2, paragraph 0020; page 3, paragraph 0036). At least a second component is a non-soluble natural collagen fiber (i.e., insoluble fibrillar collagen; see page 1, paragraph 0015) obtained from either mineralized or unmineralized collagen sources (see page 2, paragraph 0015). At least a third component is a non-porous collagen gel (see page 2, paragraphs 0024-0027). Besides maintaining physical/structural integrity and porosity after been implanted, another property of

the resulting matrix is the capability of been compressible from an initial size, shape, and porosity, and returning, from a compressed state, to its initial size, shape, and porosity (see page 3, paragraph 0031).

Said matrix further comprising: proteins, growth factors, bone marrow, and drugs (see page 2, paragraph 0022; page 3, paragraph 0037). Also, said matrix is cross-linked (i.e., glutaraldehyde; see page 2, paragraph 0028; page 3, paragraph 0032) and sterilized (i.e., ethylene oxide; see page 3, paragraph 0033). The matrix or slurry can be lyophilized (see page 2, paragraph 0028) and can also be hydrated prior to or following implantation (see page 5, paragraphs 0054-0056). Further, said matrix can be compressed during the implant procedure (see page 3, paragraph 0034) or prior to the implant procedure (see page 4, paragraph 0046). The proportions of insoluble (i.e., fibrillar mineralized or unmineralized collagen) to soluble collagen are disclosed in page 2, paragraphs 0023 and 0027. The matrix can be delivered via a delivery vehicle such as a cannula (see page 3, paragraph 0034).

Response to Arguments

9. Applicant's arguments filed November 12, 2004 have been fully considered but they are not persuasive. Applicants argue that Yamamoto et al. US 2002/0183855 implant is not plastically deformable. Examiner respectfully disagrees.

It is noted that most any material is capable of being plastically or permanently deformed if subjected to a very high stress. As disclosed in Yamamoto et al. paragraph 0037, the matrix has many applications such as tissue or cartilage repair, or osteoconductive bone grafting material for spinal fusion, filling bone defects, fracture repair, and grafting periodontal defects.

Most of these applications will present stresses to the matrix when implanted. It should be noted that "filling bone defects" and "fracture repair" comprise irregularly shaped voids or defects. What this means is that some (if not all) of the matrix covering or filling these areas will never return to its original shape and/or size. Also, Yamamoto et al. matrix comprises the same materials as Applicants' matrix, using the same ratios and consistency, and intended for the same purpose(s). The results will inherently be the same.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

11. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

February 4, 2005

David H. Willse
Primary Examiner